

REMARKS

The Official Action of July 26, 2006, portions of which are not understood, have been carefully reviewed and is generally traversed in specific regards as specified below.

The claims in the application remain as claims 1-19.

Applicant respectfully submits that these claims define novel and unobvious subject matter and should be allowed, and that the present application meets all formal requirements, again as pointed out below. Favorable reconsideration is therefore respectfully requested.

The examiner has noted that the present application is the National Stage of PCT/SE02/00951. This is correct! However, the Office Action indicates that while applicant has claimed priority, "applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b) ." Applicant does not understand! Applicant should not be required to file a certified copy because, as the present application is the National Phase of a PCT application, **the International Bureau of WIPO will have forwarded a copy of the priority application to the PTO**. Accordingly, applicant respectfully requests the PTO to acknowledge receipt of applicant's papers filed under Section 119.

Paragraph 3 on page 2 of the Official Action notes that the election/restriction requirement has been withdrawn. However, applicant has not received an examination on the merits of claims 10-19 which are indicated in the Office Action Summary as being withdrawn. **Applicant does not understand why claims 10-19 were not examined in view of the fact that the restriction requirement was withdrawn.** Applicant accordingly respectfully requests examination on the merits of claims 10-19, in view of the fact that the restriction requirement has been withdrawn.

With respect to the drawings, paragraphs 5 and 6 of the Official Action at pages 3 and 4, applicant again does not understand the position of the PTO, and therefore must strenuously traverse the objection and requirement.

The present application again is the National Phase of PCT/SE02/00951, and thus the present application was internationally filed on May 17, 2001, and a complete copy of the present application will have been forwarded to the PTO by the International Bureau of WIPO, **and that includes the drawings.** Accordingly, **there are already drawings in the present application,** and there have been from the very beginning. It is not necessary for an applicant to file courtesy copies of the drawings when entering the U.S.

National Phase. However, attached hereto are courtesy copies of the drawings, four sheets, Figs. 1-8.

The drawings indeed do show the sampling device. In fact, the drawings focus on the sampling device. Although the attached courtesy copies of the drawings from the international file are marked "substitute sheet (Rule 26)", they are the drawings which appear in the international publication WO 02/102243 A1 of the present application, copy attached.

As the attached courtesy copy of drawings are neither "replacement" drawings nor "new drawings", it would not be appropriate to mark them as either "replacement sheet" or "new sheet".

Withdrawal of the objection and requirement is respectfully requested.

The Abstract has been objected to as being too long. It has now been amended. Approval and entry and respectfully requested.

Claims 1 and 5 have been objected to for inclusion of the word "substantial" in claim 1 and for the recitation of the geometric configuration of blocking member as "bulb-formed" as recited in claim 5, and correction has been

required. The objection and requirement are respectfully traversed.

First, there is nothing wrong with the term "substantial" or "substantially", there being substantial case law in support thereof. See, for example, MPEP 2173.05(b), part D. Also see *In re Mattison et al*, 184 USPQ 484; *Charvat v. Commissioner*, 182 USPQ 577, 585-86; and the famous *Eibel* case of the United States Supreme Court at 261 US 45.

Nevertheless, applicant wishes to be co-operative, but without imposing any limitations. Accordingly, claims 1 and 5 have been cosmetically amended in deference to the examiner's views.

While "substantially bulb-formed" is believed to be clear and understandable, particularly when considering applicant's specification including Fig. 7, applicant has changed the language (based on Fig. 7) to "bell-shaped", it being noted that a cross-section through the blocking member 12 as embodied in Fig. 7 would provide a bell-shaped curve. If the examiner prefers some other language, applicant would be amenable. Thus, another equivalent expression would be "approximately dome-shaped". Another possibility would be "having a bell-shaped cross-section".

The amendments so made are clearly of a formal nature only, i.e. made to place the criticized claims in

improved form for U.S. practice or the examiner's understanding of what is necessary or desirable for U.S. practice. These amendments clearly are not "narrowing" amendments because the scope of the claims has not been reduced. No limitations have been added and none are intended.

Withdrawal of the objection is in order and is respectfully requested.

Claim 1 has been rejected under the second paragraph of §112 as allegedly claiming both an apparatus and method. Claim 1 has similarly been rejected under §101. These rejections are respectfully traversed.

**Claim 1 is directed to a sampling device. It is not directed to a method!** Applicant accordingly does not understand either of the rejections.

Is the PTO objecting to the claim preamble? The preamble recites a characteristic of the claimed sampling device, but does not, and is not intended to, recite any process.

The body of claim 1 also contains certain functional statements, but again that does not make the claim a process claim. A device may very well be characterized at least in part by functional statements. Attention is respectfully

invited to MPEP 2173.05(g), the second and third sentences of which state as follows:

There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. [citation omitted]

Withdrawal of the rejections under §§112 and 101 is respectfully requested.

Claims 1-9 have been rejected under §102 as anticipated by Pawelec USP 4,481,952 (Pawelec). This rejection is respectfully traversed.

The rejection appears to rely on the fourth embodiment of Pawelec illustrated in Figs. 12 and 13, and described at column 8, lines 28-62. This prior art is accurately discussed in the "Background" section of applicant's specification at page 2, as follows:

The [Pawelec] capsule is equipped with mechanisms, which control the opening and closing of the capsule. The mechanisms are blocked by blocking mechanisms, including a mass which is dissolved after a short time following contact with the gastric fluid. The opening of the capsule, the collection of the sample and the reclosing of the capsule takes place automatically in the patient's stomach. The described sampling device is advantageous in many ways. However, it has proved to function unsatisfactorily and has therefore not been widely used. The described capsule is expensive, is mechanically complicated and comprises

mutually movable parts, mostly metal parts. As a consequence, the parts tend to jam, fluids tend to leak between parts, friction forces between the parts must be overcome, e.g. by spring forces, and metal parts, such as springs, may loosen in the gastrointestinal tract causing injuries to the patients. [bracketed material added]

There is no question that the blocking mechanism in Pawelec includes "a mass which is dissolved after a short time following contact with the gastric fluid."

The rejection states that Pawelec discloses a blocking member (9) which "comprises an elastic material", but this is incorrect. Element 9 in Pawelec is referred to as a "valve sleeve". As regards the embodiment of Figs. 12 and 13, Pawelec states at column 8, commencing at line 37 as follows:

The opening to the chamber 18, is defined by window 16 in valve sleeve 9 and window 17 in the side wall of the inner shell member 2A.

Thereabove, at lines 34-36, Pawelec states:

The [Figs. 12-13] valve mechanism is similar to that employed in the capsule G shown and described above with reference to FIG. 1. [bracketed material added]

With reference to column 4, commencing at line 49, with reference to Figs. 1-9, Pawelec states:

A spring operated valve assembly, including valve member 9 and valve operating spring 25, is mounted within the capsule.

Thereabove, at lines 40 et seq of column 4, Pawelec states:

As will be described, upon contact with a certain fluid normally present in the alimentary canal, the mass 21 loses its effectiveness as a holding agent. This permits the shell members to be driven apart under the force of the spring 19, so that the walls of the two shell members slide along one another, eventually aperture 17 is communicated with the outside of the capsule, as shown in Fig. 6, allowing fluid, such as intestinal or gastric fluid, to be aspirated into chamber 18.

And, returning to the following paragraph commencing at line 51 of column 4, Pawelec states:

A further mass 28, having the same characteristics as mass 21, normally maintains the valve inflow permitting position, that is with aperture 16, (Fig. 3) formed in the side wall of the valve member 9 being in alignment with aperture 17. ... . When operated, the valve closes the capsule by rotating aperture 16 out of alignment with aperture 17, as shown in Fig. 7, hermetically sealing the capsule with the fluid contained within the chamber thereof.

There is not the remotest hint of any elastic blocking member or material. As correctly stated in applicant's specification on page 2, already quoted above, the blocking mechanisms comprise "a mass which is dissolved.. following contact with the gastric fluid."

The elastic properties of the blocking member in accordance with applicant's embodiments is an essential

feature of the present invention in order to achieve the stated relatively simple construction compared to the complex and unsatisfactory device of Pawelec.

Claim 3 which depends from and incorporates the subject matter of claim 1 further defines applicant's blocking member, and of course there is absolutely nothing in Pawelec which is even remotely similar.

It is unnecessary for applicants to address at this time further features in applicant's claims which additionally define over Pawelec.

Applicant's claims define novel subject matter over Pawelec, whereby Pawelec does not anticipate any of applicant's claims. Withdrawal of the rejection is therefore in order and is respectfully requested.

No rejections have been imposed under §103, and applicant agrees that there is no prior art which makes the claimed subject matter obvious. Applicant is proceeding in reliance thereof.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicant's claims.

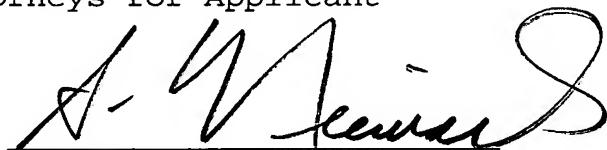
Appln. No. 10/697,943  
Amd. dated October 26, 2006  
Reply to Office Action of July 26, 2006

Applicant believes that all issues raised in the Office Action have been addressed above in a manner favorable to allowance of the present application. Accordingly, applicant respectfully requests favorable reconsideration and early formal allowance.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By



Sheridan Neimark  
Registration No. 20,520

SN:kg  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
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